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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,310	12/17/2004	Hidehito Kotani	262507US0PCT	6711

22850 7590 05/08/2007

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EXAMINER
SHAW, AMANDA MARIE

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
05/08/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/517,310	KOTANI ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-43* is/are pending in the application.

4a) Of the above claim(s) *36-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed March 30, 2007. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made FINAL.

Claims 24-43 are currently pending. Claims 24-43 are newly presented. Claims 36-43 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking Therefore Claims 24-35 will be addressed herein.

Priority

2. The English translation of Japanese Application 2002-175806 filed March 30, 2007 has been received. The Applicants submission appears to provide support for the claimed invention, however the MPEP states that when an English translation is required, it must be filed together with a statement that the translation of the certified copy is accurate (See MPEP 210.13). In the instant case the statement has not been provided, therefore the Applicants cannot rely on Japanese Application 2002-175806 for priority.

Claim Objections

3. THE FOLLOWING IS A NEW GROUND OF OBJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claims 24-27 are objected to because the claim still recites the step of determining a polymorphism of the amino acid sequence of ABCG2 polypeptide, a non-elected invention. Appropriate amendment to the claims is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Please note that the claims are being examined to the extent that they read on determining the presence of a SNP at position 421 of the ABCG2 gene.

Claims 24-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising, collecting a biological sample from said human cell and testing the biological sample from said human cell for the presence of a C421A polymorphism at nucleotide position 421 of SEQ ID NO: 1, wherein the presence in said DNA sample of said mutation at position 421 indicates a decreased capability of said human cell for excreting Compound B, does not reasonably provide enablement for a method comprising, determining whether a mammalian cell

has a polymorphism at position 421 of the ABCG2 gene of SEQ ID NO: 1, wherein the presence of a polynucleotide polymorphism at position 421 is indicative of altered drug transport capability of said mammalian cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Breadth of the Claims:

Claim 24 is drawn broadly to a method for predicting the drug transport capability of a mammalian cell. The claim reads on any type of cell transport (moving in or out), any drug, any mammal, and any allele at position 421 of the ABCG2 gene. Claims 25-27 are drawn to drugs which have the indolocarbazole structure (specifically Compound A and Compound B). Claims 28-30 are drawn to different types of mammalian cells. Claims 31-35 are drawn to methods for detecting polymorphisms.

Nature of the Invention

The claims are drawn to methods for predicting a drug transport capability of a mammalian cell. The invention is in a class of inventions which the CAFC has

characterized as 'the unpredictable arts such as chemistry and biology" (Mycolgen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Federal Circuit 2001)).

Teachings in the Specification and State of the Art:

The specification teaches on page 3 that SEQ ID NO 1 represents the ABCG2 gene. It is noted that SEQ ID NO 1 actually only represents the coding regions of the ABCG2 gene and not the entire gene. The specification on page 35 further teaches 2 mutations in the ABCG2 gene (G34A and C421A) that result in amino acid substitutions in the ABCG2 protein that have a high possibility to affect the function of the ABCG2 polypeptide. Additionally the specification teaches that one mutation (C376T) codes for a stop codon and does not even produce a functional protein. The specification does not teach any other variations in the ABCG2 gene which are associated with drug transport capability. The specification also teaches a chemical structure on page 3. The specification states that this structure belongs in the class of indolocarbazole compounds and that the protein encoded by SEQ ID NO 1 confers a selective resistance to indolocarbazole compounds. The specification specifically provides data on the association between the SNP at position 421 and an indolocarbazole compound called “Compound B”. The specification does not teach any other additional indolocarbazole compounds that are associated with the SNP at position 421. Further it is noted that page 3 of the specification teaches the chemical structure of compounds A and B. The specification further teaches on page 5 that the inventors analyzed genomic DNA extracted from many human cancer cell lines and clinical samples and identified single nucleotide polymorphisms in the ABCG2 gene. Thus the specification does not

teach any other types of samples being collected from any other types of mammals other than DNA from humans.

The Predictability or Unpredictability of the Art and Degree of Experimentation:

Further, it is unpredictable as to whether the results obtained in human subjects could be extrapolated to other mammals. Knowledge that mutations in a gene occur in one mammal (i.e. humans) does not allow one to conclude that this gene, and mutations in this gene will also occur in other mammals. The specification does not teach homologues of the ABCG2 gene in a representative number of different mammals. In the absence of information regarding the functional properties of the ABCG2 gene and the disclosed mutations in this gene, it is unpredictable as to whether the ABCG2 gene, and particularly the C421A mutation, will also be present in other mammals and can be used to predict transport capability of drugs.

It is also unpredictable as to whether the results obtained with Compound B can be extrapolated to other drugs particularly other indolocarbazole compounds. The teachings in the specification are limited to an association between the 3 mutations and the transport capability of Compound B. There are no teachings in the specification regarding how these 3 mutations affect the transport capability of other drugs particularly other indolocarbazole compounds. The post filing date art of Sanchez et al (J Ind Microbiol Biotechnol) teaches that there are hundreds of indolocarbazole derivatives and several of them have entered clinical trials for the treatment of diverse types of cancer. Sanchez further teaches that the distinct structural features of each type of indolocarbazole derivative results in one of or several of the following

mechanisms (a) inhibition of different protein kinase (b) inhibition of DNA topoisomerase or (c) direct DNA intercalation (Page 560). Accordingly, it is unpredictable as to whether the presently claimed method can be used to predict the transport capability of any drug particularly any indolocarbazole compound given the diverse activities of each of these drugs.

Amount of Direction or Guidance Provided by the Specification:

The specification teaches that the C421A variant of the ABCG2 gene is associated with decreased capability of excreting Compound B from human cells. To identify whether additional drugs will also be decreased at a lower rate from a cell would require extensive experimentation. Such random, trial by error experimentation is considered to be undue. The results of performing such methodology is highly unpredictable. The specification has provided only an invitation to experiment. The specification does not provide a predictable means for identifying additional variants of the ABCG2 gene which can be used to predict transport capability of compound B.

Working Examples:

There are no specific examples provided in the specification in which any other variants of the ABCG2 gene were found that could be used to predict transport capability. Additionally there are no specific examples where non-human mammals were used. Further there are no specific examples provided in the specification in which these mutations can be used to predict transport capability of other drugs besides Compound B.

Conclusions:

Case law has established that '(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that '(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that '(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

In the instant case, the claims do not bear a reasonable correlation to the scope of enablement because the specification teaches 3 mutations within the ABCG2 gene that can be used to predict transport capability of Compound B. The specification does not teach a representative number of additional variants of the ABCG2 gene which can be used to predict transport capability. Further the specification does not teach the affect of these mutations on the transport capability of other drugs particularly other types of indolocarbazole compounds. Additionally, the disclosure of a single mammal, humans, in which mutations in the ABCG2 gene can be used to predict transport capability is not representative of the broadly claimed genus of all mammalian subjects. Accordingly, although the level of skill in the art of molecular biology is high, given the lack of disclosure in the specification and in the prior art and the unpredictability of the

art, it would require undue experimentation for one of skill in the art to make and use the invention as broadly claimed.

Response to Arguments

5. In the response filed March 30, 2007, Applicants cancelled claims 1-4, 8, and 20-21 which were rejected as lacking adequate enablement. The Applicants argue that the enablement rejection would not apply to the newly filed claims because no undue experimentation would be required to make and use the invention. This argument has been fully considered but is not persuasive for several reasons. First the claims are not enabled because claim does not recite a step of obtaining a biological sample and testing said sample for the presence of the C421A polymorphism. Without this step, the claim encompasses a method of performing nucleic acid analysis on a sample to determine the presence of the polymorphism as mentally just looking at a subject genotype and determining the presence of the polymorphism. The claims also lack enablement because the claimed invention is drawn to any mammalian cell. The Applicants have not shown the method of the instant invention to be useful in any mammal especially since the specification does not teach homologues of the ABCG2 gene in any other non-human mammal. Therefore it is unpredictable whether the instant invention would be useful for any mammal because it is uncertain as to whether the ABCG2 gene, and particularly the C421A mutation, will also be present in other mammals and can be used to predict transport capability of drugs. The claims also lack enablement because they do no not recite the specific polymorphic allele at position 421

that is indicative of altered drug transport capability. Therefore the claims encompass detecting any nucleotide (A, C, G, or T) at position 421 wherein the detection of allele is indicative of altered drug transport capability. This can be overcome by amending the claims to recite, i.e. "determining whether a human cell has a C421A polymorphism at position 421 of SEQ ID NO: 1". Further the claims lack enablement because they encompass predicting the transport capability of any drug in a mammalian cell. However the specification only teaches an association between the C421A polymorphism of the ABCG2 gene and the ability of a human cell to excrete "Compound B". Findings that transport of "Compound B" is affected by the C421A polymorphism cannot be extrapolated in any drug, particularly indolocarbazoles. Finally the claims lack enablement because they encompass any cell transport activity. The Office recognizes that some polymorphisms are associated with decreased drug transport or accumulation of drugs inside a cell, while other are associated with decreased accumulation of drugs. However in the instant case the Applicants have shown that the C421A polymorphism is only associated with a decreased ability for excreting Compound B. The Applicants have not shown that the C421A polymorphism of the ABCG2 gene is associated with any other drug transport activity. For these reasons the enablement rejection still applies to the amended claims as filed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claims 24-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-35 are indefinite over the recitation of the phrase "at position 421 of the ABCG2 gene of SEQ ID NO: 1". This phrase in considered indefinite because SEQ ID NO 1 appears to only represent the coding sequence of ABCG2 gene and not the full length sequence of the ABCG2 gene.

Claims 24-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that the goal of the method and the final step do not agree. The claims are drawn to methods for predicting a drug transport capability of a mammalian cell. However, the claims recite the final step of determining whether a mammalian cell has a polymorphism. The steps listed in the method do not result in predicting a drug transport capability. Therefore, it is unclear as to whether the claims are intended to be limited to methods for predicting drug transport capability or methods for determining whether a mammalian cell has a polymorphism.

Claim 26 is indefinite over the recitation of the phrase "Compound A". This phrase in considered unclear because “Compound A” is not defined by the claim or the specification, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 27 is indefinite over the recitation of the phrase "Compound B". This phrase in considered unclear because "Compound A" is not defined by the claim or the specification, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 32 contains the trademark/trade name Taqman™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a type of nucleic acid amplification method and, accordingly, the identification/description is indefinite.

Claim 33 contains the trademark/trade name Invader™ method. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or

trade name. In the present case, the trademark/trade name is used to identify/describe a type of nucleic acid amplification method and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Please note that the claims are being examined to the extent that they read on determining the presence of a SNP at position 421 of the ABCG2 gene.

Claims 25, 28-31, and 35 are rejected under 35 U.S.C. 102(a) as being anticipated by Imai et al (Molecular Cancer Therapeutics June 2002).

Imai et al teach that the C421A polymorphism of the BCRP gene (also known as ABCG2) is associated with decreased protein expression and low level drug resistance by pumping out a variety of antitumor drugs (i.e. SN-38, mitoxantrone, and topotecan) from cells (Page 611). Imai et al sequenced the whole coding sequence of BCRP cDNA (Accession number AF103796) in 11 cancer cell lines and identified three SNPs including the C421A SNP and investigated functional outcomes. The incidence of the

C421A SNP was also examined in blood samples derived from healthy Japanese volunteers.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Please note that the claims are being examined to the extent that they read on determining the presence of a SNP at position 421 of the ABCG2 gene.

9. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imai (Molecular Cancer Therapeutics June 2002) in view of Komatani et al (Cancer Research 1/2001).

The teachings of Imai et al are presented above.

Imai et al does not teach that the C421A SNP of the ABCG2 gene is associated with the drug transport capability of indolocarbazole compounds, specifically "Compound A" and "Compound B".

However Komatani et al teach that small differences in the amino acid sequences of the BCRP gene (also known as AGCG2) may explain differences in the transport capability of indolocarbazole compounds in cells (Page 2831). Further the instant specification states that Komatani et al teaches that the accumulation of Compound A and Compound B is selectively suppressed by the BCRP gene (see spec page 4).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Imai et al by further seeing if this mutation effects the transport capability of indolocarbazole compounds as suggested by Komatani for the benefit of identifying additional mutations in the BCRP gene that are associated with the transport capability of indolocarbazole compounds. Komatani et al speculates that small changes in the amino acid sequence of BCRP (such as the Gln141Lys change caused by the C421A transversion) cause changes in substrate specificity and may explain why some people are resistant to these drugs (Abstract and page 2831).

10. Claims 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imai (Molecular Cancer Therapeutics June 2002) in view of Kwok et al (US Patent 5945283 Issued Aug 1999).

The teachings of Imai et al are presented above.

Imai et al does not teach a method wherein the polymorphism is detected using a Taqman method.

However Kwok et al teach that on application of the Taqman assay is in detecting SNPs (column 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Imai et al by detecting the polymorphism using a Taqman assay as suggested by Kwok for the benefit of using an assay that is automated and does not a lot of labor.

11. Claims 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imai (Molecular Cancer Therapeutics June 2002) in view of Brow et al (US Patent 5846717 Issued Dec. 1998).

The teachings of Imai et al are presented above.

Imai et al does not teach a method wherein the polymorphism is detected using an invader method.

However Brow et al teach that invader directed cleavage reactions are useful in the detection and quantification of individual variant or alleles in a mixed sample population (Column 35).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Imai et al by detecting the polymorphism using an Invader assay as suggested by Brow in instances when it is desirable to not only detect mutations which exist within a target molecule but to also determine the relative concentrations of each sequence (i.e., mutant and wild type) present within samples containing a mixture of target sequences.

12. Claims 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imai (Molecular Cancer Therapeutics June 2002) in view of Lizardi et al (US Patent 5854033 Issued December 1998).

The teachings of Imai et al are presented above.

Imai et al does not teach a method wherein the polymorphism is detected using RCA.

However Lizardi et al teach that multiplex RCA assays are particularly useful for detecting mutations in genes where numerous distinct mutations are associated with certain diseases or where mutations in multiple gene are involved (Column 22).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Imai et al by detecting the

polymorphism using RCA as suggested by Lizardi. Major advantages of this method are that the ligation step can be manipulated to obtain allelic discrimination, the DNA replication step is isothermal, and signals are strictly quantitative because the amplification reaction is linear and is catalyzed by a highly processive enzyme. In multiplex assays, the primer oligonucleotide used for the DNA polymerase reaction can be the same for all probes (Abstract).

Response to Amendment

14. It is noted that the applicants have filed papers which establish that the Imai reference was not publicly available until June 18, 2002. This has been confirmed by the PTO STIC. Therefore, if the Applicants are able to perfect their priority claim, then the rejections made over the Imai reference will be dropped.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

DIANA JOHANNSEN
PRIMARY EXAMINER